

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of effect of the topical product of Cassia fistula on diaper rash of infants in comparison with hydrocortisone: a double-blind clinical trial

Protocol summary

Study aim

A) The main goal of the plan Determining the effect of Flos topical product on diaper inflammation in children, compared to treatment with hydrocortisone b) Sub-objectives of the plan. 1 Investigating the effect of Flos topical product on the duration of treatment

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 168 patients. Randomization using permuted block randomization method will be used

Settings and conduct

The evaluation of people entering the study is done by a doctor specializing in children and infants

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Boys and girls under two years old 2. The presence of signs of diaper inflammation Exit criteria: 1. Presence of atopic dermatitis and related underlying diseases and other skin diseases 2. Using other treatments related to diaper inflammation two weeks ago 3. Severe type or score higher than 3 4. Drug sensitivity 5. Diarrhea 6 oral use of antibiotics

Intervention groups

This study is a double-blind randomized clinical trial study with a control group and a parallel design. The evaluation of people entering the study is done by a doctor specializing in children and infants, and in case of clinical suspicion that there is a severe disease and severe bacterial and fungal infections that have led to local inflammation (severe type or a score higher than 3) is removed from the study and is subjected to standard treatment. Every person who meets the criteria for entering the study is evaluated by an Iranian medical expert using the Ddsis tool (diaper dermatitis severity index score) in the first and subsequent visits and with this tool The score of the patient is determined.

Main outcome variables

Duration of treatment; intensity of redness; extent of redness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230314057713N1**

Registration date: **2023-04-07, 1402/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-07, 1402/01/18**

Update count: **0**

Registration date

2023-04-07, 1402/01/18

Registrant information

Name

Mozafar Ekhlasi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2024-01-04, 1402/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of effect of the topical product of Cassia fistula on diaper rash of infants in comparison with hydrocortisone: a double-blind clinical trial

Public title
The effect of cassia fistula product

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Infants under two years old age Inflammation of diaper area
Exclusion criteria:
 Atopic dermatitis and other skin dermatitis Other diaper rash treatment from 2 weeks ago Sever type or inflammation with above score 3 Drug sensivity Diarrhea Oral antibiotic consumption

Age
From **1 day** old to **2 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **138**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using the method of random permutation blocks. The size of the blocks is 4 and the ratio of drug to control (hydrocortisone ointment) in each group is equal (1:1). In each block, random permutations of 4 combinations of Flos and hydrocortisone formulations are considered.

Blinding (investigator's opinion)
Double blinded

Blinding description
Cassia fistula product ointment and hydrocortisone will be packed and coded in a single form with the same consistency and color and smell (with the addition of color and essential oil) with the same label by a pharmaceutical specialist in the medicinal plant laboratory of the Iranian Medicine School of Babol. The only person who knows the nature of the drugs is the pharmacist who manufactures the drug. Random codes are written on the boxes containing the drug (floss/hydrocortisone product) and after assigning the drug to the patients, the relevant code is recorded on the patient's file. to be The opening of the codes will be done after the end of the study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Keshavarz Street, University Square, Babol University of Medical Sciences

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Mazandaran

Postal code

47176-47754

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.256

Health conditions studied

1

Description of health condition studied

Inflammation of the diaper area

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of treatment

Timepoint

each day

Method of measurement

Counting days

2

Description

intensity of redness

Timepoint

Counting days

Method of measurement

diaper dermatitis severity index score

3

Description

The extent of redness
Timepoint
Counting days
Method of measurement
Percentage of diaper area

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The evaluation of people entering the study is done by a doctor specializing in children and infants, and in case of clinical suspicion that there is a severe disease and severe bacterial and fungal infections that have led to local inflammation (severe type or a score higher than 3) is removed from the study and is subjected to standard treatment. Every person who meets the criteria for entering the study is evaluated by an Iranian medical expert using the Ddsis tool (diaper dermatitis severity index score) in the first and subsequent visits and with this tool The score of the patient is determined. According to the summary of studies, the average recovery period is 7 days. The patients were followed up every day according to the assistant's phone call with the mother and based on the changes with the initial examination, and according to the in-person examination by the assistant on the first, fourth and seventh days, the changes in the score index were measured at the beginning and then at the end of the treatment, and statistically, between Two groups are compared. The duration of treatment is also evaluated

Category

Treatment - Drugs

2

Description

Control group: The evaluation of people entering the study is done by a doctor specializing in children and infants, and in case of clinical suspicion that there is a severe disease and severe bacterial and fungal infections that have led to local inflammation (severe type or a score higher than 3) is removed from the study and is subjected to standard treatment. Every person who meets the criteria for entering the study is evaluated by an Iranian medical expert using the Ddsis tool (diaper dermatitis severity index score) in the first and subsequent visits and with this tool The score of the patient is determined. According to the summary of studies, the average recovery period is 7 days. The patients were followed up every day according to the assistant's phone call with the mother and based on the changes with the initial examination, and according to the in-person examination by the assistant on the first, fourth and seventh days, the changes in the score index were measured at the beginning and then at the end of the treatment, and statistically, between Two groups are compared. The duration of treatment is also evaluated

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان کودکان امیر کلا بابل

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available